ERWEKA-DISSOLUTION APPARATUS

OBJECTIVE

- To estimate/determine potential drug dissolution/release characteristics of a drug from a product using a simulated gastrointestinal (GI) tract fluid or a predetermined solution.

SCOPE

- Dissolution apparatus is used in the pharmaceutical industry to determine the rate at which pure active pharmaceutical ingredients dissolve.

RESPONSIBILITIES

- It is the responsibility of designated personnel in Research lab to train staff and students on this procedure and to ensure adherence to this procedure.
- It is the responsibility of designated personnel (staff or Student) to follow the instructions of this procedure.

REFERENCES

- Instruction Manual (Operation Guide) Erweka company for Dissolution apparatus.

PRECAUTIONS

- Note the parts of the assembly, including the environment in which the assembly is placed, contributes significant motion, agitation, or vibration beyond that due to the smoothly rotating stirring element.

OPERATING PROCEDURE

- **Stirring Element Height** —Set the distance between the bottom of the vessel's inner surface and the lower part of the stirring element. Use height gauges to check the distance between the bottom of the vessel and stirring element. Measure the distance for each vessel position. Some test assemblies allow the height of the stirring element to be set before beginning the test. All values must be within 23.0 and 27.0 mm.
- **Baskets**—Place one tablet in each dry basket. Attach the basket to its shaft. The test is considered to start when the basket is immersed in the medium at the prescribed height. Immediately start the stirring.
- **Paddles**—Allow the tablet to fall into the vessel in a standardized manner, e.g. along the vessel wall or at the center of the vessel along the paddle shaft. The test is considered to start when the tablet comes to rest at the bottom of the vessel. The most reproducible conditions will exist with the sample settled directly under the paddle shaft (e.g., on the vessel axis). Immediately start the stirring.
- **Timing**—Record the start time of the dissolution test using a calibrated timing device. The type of starting procedure must allow for sample collection and filtration of all positions within the current ± 2% tolerance limit for time (± 36 seconds for a 30 minute run). The time needed to sample each vessel may be accommodated with a staggered start allowing a minimal start-time interval between vessels and is recommended if possible.
- **Observations**—Carefully record any visual observations of the dissolution test, such as basket wobble, air bubble formation, or the condition or motion of the disintegrating tablet particles.
- Sampling—Withdrawal and filtration of the sample aliquot conclude the test interval. After 30 minutes of testing and with rotation continuing, withdraw a portion of the dissolution medium from each vessel, about 30 mL. Sample from a zone midway between the surface of the dissolution medium and the top of the basket or top of the paddle blade, not less than 1 cm from the vessel wall.
- Filter each sample immediately through a syringe filter (0.45-µm PVDF-type or equivalent), discarding the first 5 mL portion of filtrate. [Note: Equivalent filters will provide filtrate with analytical response within 1% of the unfiltered solution. Discard volume is a function of the filter and may not be identical to that recommended in this document.] Cool the filtered dissolution samples to ambient temperature prior to UV analysis (sample and standard solutions are at the same temperature). Do not centrifuge the sample. A separate unused filter, cannula, and clean syringe should be used for each vessel.

Automated Sampling

- If used, automated sampling methods and filter probes should be validated against the manual sampling method. Variables include, carry over from system surfaces exposed to test solution, dwell time for on-line spectrophotometric analysis, and filter interference.

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